REMARKS

I. Introduction

This Amendment is responsive to the November 21, 2006 final Office Action and is accompanied by a Petition for Three-Month Extension of Time and Request for Continued Examination for entry and consideration of this Amendment is respectfully requested. Initially, the specification stands amended to place it in better form and correct certain inconsistencies relating to inventorship (i.e., one inventor as opposed to multiple as inadvertently identified in the body of the specification).

With respect to the claims, claims 1, 5-6, 8-12, 16-17, and 19-20 are now pending in this Application. Applicant has cancelled withdrawn claims 2-3, 13-14, and 21-28 and reserves the right to file a divisional application on the subject matter of these withdrawn claims. Claim 15 is cancelled as suggested in the final Office Action and claims 5, 8-9, 16, and 19-20 have been amended for proper dependency from claims 1 and 12, respectively. The change in dependency of claims 8-9 and 19-20 is a result of the clarifying changes made to independent claims 1 and 12 discussed herein.

It is noted that Applicant has amended claims 6 and 17 to re-include temporomandibular joint pain and bruxism as respective possible symptoms of a function somatic syndrome in the listings in claims 6 and 17 as there does not appear to be any apparent confusion regarding these two specific ailments relative to the disclosure of the cited patents in the final Office Action as discussed in Applicant's Amendment dated September 18, 2006. As a result, the removal of temporomandibular joint pain and bruxism from the listings in claims 6 and 17 in Applicant's Amendment dated September 18, 2006 was not necessary for patentability and this Amendment corrects the previous deletion of these claim terms. Accordingly, Applicant's previous removal of these claim terms should not be read as limiting the scope of claims 6 and 17.

Additionally, Applicant has deleted from claim 11 the recitation of sleep onset insomnia and sleep maintenance insomnia as functional somatic syndromes for clarification purposes only. These deletions are made so that the listing of functional somatic syndromes in claim 11 comports with listings found in the medical literature. Moreover, Applicant provides

herewith a Declaration Under 37 C.F.R. § 1.132 by an expert in the field of Sleep Medicine, Dr. Mark H. Sanders, to address the claim rejections under 35 USC § 112, first paragraph, and 35 USC § 103(a).

II. Clarifying Amendments – Independent Claims 1 and 12

As noted in the foregoing, certain claim amendments have been made to independent claims 1 and 12 for clarification purposes. These claim amendments introduce an additional step in the methods of treating functional somatic syndromes of claims 1 and 12 in the form of "determining whether a patient suffers from inspiratory airflow limitation during sleep". The treatment step in claims 1 and 12 is further clarified as an "upper" airway stabilization technique, again for clarification purposes only. These changes clarify in independent claims 1 and 12 Applicant's general contention set forth in the specification that there is a nexus between inspiratory airflow limitation during sleep and the functional somatic syndromes and that by treating this likely root cause, treatment of the functional somatic syndromes is accomplished. These changes merely conform independent claims 1 and 12 with the disclosure in the specification relating to a nexus between inspiratory airflow limitation during sleep and the functional somatic syndromes and do not narrow the scope of independent claims 1 and 12. It is noted that the specification provides ample support in numerous location for Applicant's foregoing clarifications, (See paragraphs [0009], [0022] and [0057]) and as further pointed out in Paragraph 5 in the accompanying Declaration Under 37 C.F.R. § 1.132 signed by Dr. Mark A. Sanders (hereinafter the "Sanders Declaration"), an expert in the area of Sleep Medicine. Thus, the foregoing clarifying changes merely help tie the "treatment" step present in independent claims 1 and 12 to the likely cause of the functional somatic syndrome as set forth in detail in the specification.

III. 35 USC § 112, First Paragraph, Claim Rejections

Claims 1, 4-12, and 15-20 stand rejected under 35 USC § 112, first paragraph, for alleged non-enablement. The final Office Action states that:

> the specification, while being enabling with regard to a method of treating the particular functional somatic syndrome of fibromyalgia, UARS and OSA/H, does not reasonably provide enablement for treating other functional somatic syndromes such as chronic fatigue syndrome, irritable bowel syndrome, migraine headaches, tension headaches,

> temporomandibular joint syndrome, Gulf War syndrome, premenstrual syndrome, multiple chemical sensitivity, sick building syndrome, repetition stress injury, side effects of silicone breast implants, chronic whiplash, restless leg/periodic limb movement syndrome.

Applicant respectfully traverses these rejections.

The test for enablement is whether the specification provides sufficient information to one skilled in the art to make and use the claimed invention without undue or unreasonable experimentation. (MPEP §2164.01) Applicant respectfully submits that the specification provides full and complete support for the practice of the claimed methods of treating a full range of functional somatic syndromes without undue or unreasonable experimentation. The specification clearly identifies a definition of functional somatic syndromes (FSS) as being physical syndromes without an organic disease explanation, demonstrable structural changes, or established biochemical abnormalities. (See paragraph [0005]). This lack of any explanatory cause or physical or biochemical change or abnormality is what links these disorders together under the title "functional somatic syndromes". The specification then identifies a (medical literature-accepted) listing of functional somatic syndromes to include: chronic fatigue syndrome, fibromyalgia, irritable bowel syndrome, migraine headaches, tension headaches, temporomandibular joint syndrome, premenstrual syndrome, multiple chemical sensitivity, sick building syndrome, repetition stress injury, side effects of silicone breast implants, Gulf War syndrome, chronic whiplash, and restless leg/periodic limb movement syndrome, (See paragraph [0005]). Applicant's specification clearly articulates his thesis statement that inspiratory airflow limitation during sleep has a likely underlying or unifying role in the development of the functional somatic syndromes and can be treated by correcting this inspiratory airflow limitation during sleep, (See paragraphs [0009], [0022] and [0057]). This is accomplished as disclosed in the specification by stabilizing the upper airway of the patient using one or more kinds of upper airway stabilization devices or techniques, (See paragraph [0025]). Exemplary devices/apparatus for use in upper airway stabilization via positive airway pressure therapy is provided in the specification in paragraph [0026], (CPAP), and paragraph [0029] provides examples of mechanical airway stabilization. Moreover, the specification enumerates clearly in several locations, (See, for example,

paragraphs [0022], [0056], [0066]), that treatment of inspiratory airflow limitation during sleep may be used to treat the functional somatic ***syndromes*** and, therefore, is not confined to treating any one of the individual functional somatic syndromes, such as fibromyalgia.

In the specification, in one exemplary embodiment, the treatment platform or technique used in the functional somatic syndrome treatment methods is a mechanical stabilization technique, typically a device in the form of an oral appliance. In another exemplary embodiment, the treatment platform or technique used in the treatment methods is a positive airway pressure device and, in one suitable example, a CPAP device. The treatment methods and exemplary apparatus, platforms, techniques used therein are disclosed in the specification as being suitable for treatment of the functional somatic ***syndromes***, as clearly stated in paragraphs [0022], [0056], and [0066] of the specification. The treatment methods and exemplary treatment apparatus, platforms, techniques are not limited solely to the treatment of fibromyalgia as set forth in non-limiting Example II beginning on page 17 of the specification. Accordingly, in summary, the specification fully describes and fully supports one or more treatment methods and identifies suitable apparatus, platforms, techniques for accomplishing, at least in part, these treatment methods for treating the functional somatic ***syndromes*** or symptoms as claimed in independent claims 1 and 12. The treatment methods disclosed in the specification and exemplary apparatus, platforms, techniques used in the treatment methods may be used to treat any one of the individual functional somatic ***syndromes*** enumerated in paragraphs [0005] and [0023], as prominently stated in paragraphs [0022], [0056], and [0066] of the specification.

Provided herewith is the Sanders Declaration wherein an expert in Sleep Medicine, Dr. Mark A. Sanders, concludes that the specification fully enables the claimed treatment methods without undue or unreasonable experimentation. In the Sanders Declaration, Dr. Sanders concludes that the specification teaches that a patient suffering from inspiratory airflow limitation followed by an identification or determination of the presence of a functional somatic syndrome (or one or more symptom thereof) could be treated by the methods and apparatus disclosed in the specification without undue or unreasonable experimentation. He additionally concludes that it would be understood by one skilled in the art, after reading Applicant's disclosure, that the disclosed methods and apparatus are not intended to be limited to

the treatment of fibromyalgia as in Example II but are intended to treat functional somatic syndromes generally once inspiratory airflow limitation during sleep has been identified in a patient. Dr. Sanders further concludes that one skilled in the art would not be required to perform undue or unreasonable experimentation based on Applicant's disclosure to apply the claimed methods and apparatus to a specific functional somatic syndrome or syndromes and would recognize that the specific fibromyalgia example, Example II, beginning on page 17 of the specification, is merely a representative example for treating any individual functional somatic syndrome as this is the intent of Applicant's disclosure. He concludes his comments on the enablement question by stating:

> I find that it is quite clear that the methods and apparatus identified in Dr. Gold's disclosure may be used, without undue or unreasonable experimentation, to treat a patient identified as suffering from any of the functional somatic syndromes or symptom(s) thereof once upper airway limitation during sleep has been determined in the patient.

The Sanders Declaration also confirms that those skilled in the medical art are capable of identifying a patient as suffering from a functional somatic syndrome as part of their expertise in the medical field.

In view of the foregoing and the accompanying Sanders Declaration, it is respectfully submitted that undue or unreasonable experimentation is not required to practice the claimed methods of treating functional somatic syndromes or symptom(s) thereof and, in fact, the specification fully teaches how to treat any one of the functional somatic syndromes using an airway stabilization technique, which can take the form of mechanical airway stabilization or positive airway pressure stabilization as non-limiting examples. In light of the complete teaching in the specification as how to practice the claimed methods and the evidence provided in the accompanying Sanders Declaration, reconsideration and withdrawal of the rejections under 35 USC § 112, first paragraph, are respectfully requested.

IV. 35 USC § 103(a) Claim Rejections

Claims 1, 5, 6, 7, 11, 12, and 15-18 stand rejected under 35 USC § 103(a) for obviousness over United States Patent No. 6,769,910 Pantino in view of Thornton. Claims 8, 9,

19, and 20 stand rejected under 35 USC § 103(a) for obviousness over Pantino in view of United States Patent No. 5,954,048 to Thornton, and further in view of United States Patent No. 6,752,766 to Kowallik et al. Claim 10 stands rejected under 35 USC § 103(a) for obviousness over Pantino in view of United States Patent No. 5,378,686 to Bennett. In view of the following remarks, reconsideration of all of these rejections is respectfully requested.

With respect to the cited references, Pantino discloses a non-surgical oral appliance for improving breathing, and abating or completely alleviating snoring sounds, temporomandibular joint syndrome ("TMJ"), and bruxism while sleeping. As discussed in the background section of Pantino, (See column 2, lines 1-12), TMJ has been associated with a wide variety of physical ailments, including migraine headaches. Most people afflicted with TMJ suffer from a myofacial pain dysfunction syndrome manifested primarily as a muscle problem related to dental/skeletal relationships and tensional factors. The effects of TMJ can range from mild to severe, including pain in the joint area that can extend to the shoulders, back, and neck, and sinus.

Thornton discloses a device (10) adapted for a connection to a continuous positive air pressure ("CPAP") system (88) and which includes a mouthpiece formed by a pair of upper and lower arches (12, 14). Kowallik discloses a method and device for sleep monitoring. Bennett discloses a therapeutic treatment for fibromyalgia.

It is noted that the claimed treatment methods in claims 1 and 12 are now limited to the use of positive airway pressure therapy as the airway stabilization technique due to an earlier election/restriction requirement in this Application. However, Applicant is of the belief that his method of treating functional somatic syndromes with mechanical upper airway stabilization is also patentable over the cited references and is properly the subject of a divisional application. No adverse conclusion should be drawn from Applicant's discussion of and specific reference to positive airway pressure therapy hereinafter.

Pantino discloses nothing more than a conventional lower jaw (i.e., mandible) repositioning device, an "oral appliance", for treating snoring and/or sleep apnea. Such conventional oral appliances adapted for mandibular repositioning are well-known in the Sleep Medicine field and similar examples of which are, in fact, identified in Applicant's specification

in paragraphs [0029-0030]. Paragraph [0030], in particular, provides specific examples of suitable mandibular repositioning oral appliances which may be used in Applicant's claimed treatment methods to mechanically stabilize a patient's upper airway by mandibular repositioning. It is also well-known that such mandibular repositioning oral appliances often have a benefit of treating the physical symptoms associated with TMJ and bruxism due to the fact that such oral appliances reposition the lower jaw, separate the upper and lower jaw, and fix the lower jaw relative to the upper jaw while sleeping. Such mechanical mandibular repositioning oral appliances are, therefore, known to alleviate the physical symptoms of TMJ and bruxism essentially because they are dental appliances that are inserted within the human mouth and will prevent these physical symptoms from manifesting themselves in the first instance by restricting the movement of the lower jaw. However, it is incorrect to conclude that, just because such oral appliances additionally treat the symptoms of TMJ and bruxism, that the claimed methods in independent claims 1 and 12 would have been obvious over Pantino alone or in combination with Thornton. This conclusion cannot be sustained because Pantino and Thornton do not teach or suggest any possible causal connection or linkage between restricted or limited inspiratory airflow during sleep and the functional somatic syndromes which may be addressed via upper airway stabilization pursuant to Applicant's disclosure. Only Applicant identifies the likely role of inspiratory airflow limitation during sleep and the functional somatic syndromes of which TMJ and bruxism are members. In fact, the Pantino disclosure is limited to merely incidentally teaching that the physical symptoms of TMJ and bruxism may be reduced or eliminated by use of the Pantino mechanical oral appliance by "fixation of the mandible", (See Pantino column 5, lines 24-27). This, again, is a known recognized benefit of prior art mandibular repositioning oral appliances as has been explained previously. Applicant's finding that the functional somatic syndromes can be treated through stabilization of the patient's upper airway with positive airway pressure therapy and/or mechanical stabilization is a pioneering recognition in the medical field.

The accompanying Sanders Declaration substantiates many of the foregoing facts regarding the Pantino disclosure. The Sanders Declaration makes clear that Pantino-type oral appliances are well-known for treating sleep-disordered breathing and often have a benefit of

treating the physical symptoms associated with TMJ and bruxism due to the fact that the oral appliance repositions the lower jaw, separates the upper and lower jaw, and fixes the lower jaw relative to the upper jaw while sleeping. It is Dr. Sanders belief that one skilled in the art would understand that the Pantino disclosure and the oral appliance disclosed therein is directed primarily to treatment of sleep disordered breathing by the physical repositioning of the lower jaw and that the additional benefit of this repositioning is the reduction of the symptoms of TMJ and bruxism in the patient by "minimizing the negative effects of a static positioning of the: 1) teeth and related muscles and ligaments", (See Pantino column 4, lines 63-64). Accordingly, as stated in the Sanders Declaration, there is nothing in the Pantino disclosure relating to a causal connection or linkage between inspiratory airflow limitation during sleep as a likely underlying or unifying cause of the functional somatic syndromes as per Applicant's disclosure and, thus, no recognition on the part of Pantino that his mechanical oral appliance would in any way be applicable to or capable of treating the functional somatic syndromes. The Sanders Declaration further indicates that the fact that the Pantino oral appliance can additionally treat the symptoms of TMJ and bruxism in no way leads one skilled in the art to conclude that it can be used to treat functional somatic syndromes generally. Thus, the Sanders Declaration concludes that the claimed treatment methods are not taught or suggested by Pantino.

Moreover, the Sanders Declaration rebuts the position in the final Office Action regarding combining the CPAP aspects of Thornton with the Pantino oral appliance. The Sanders Declaration states that one skilled in the art would not be motivated in any way to add a positive airway pressure component to the Pantino mechanical oral appliance for treatment of TMJ and bruxism as the mechanical oral appliance itself provides the benefit of treating the symptoms associated with TMJ and bruxism by repositioning the lower jaw (i.e., mandible), and the addition of a positive airway pressure therapy component would add nothing to the treatment of TMJ and bruxism and, consequently, would be unnecessary. Finally, Dr. Sanders respectfully disagrees with the general contention in the final Office Action that it would be obvious to one skilled in the art to add a positive airway pressure component to the Pantino oral appliance for the treatment of the functional somatic syndromes. He states that only Applicant's Application identifies a causal connection between inspiratory airflow limitation during sleep and the

functional somatic syndromes and further teaches the corrective regimen of upper airway stabilization, whether by mechanical means and/or positive airway pressure therapy means. Pantino and Thornton do not even hint to such a connection.

In view of the foregoing, Applicant respectfully submits that there is nothing in the Pantino disclosure relating to a causal connection or linkage between inspiratory airflow limitation during sleep as a likely underlying or unifying cause of the functional somatic syndromes as per Applicant's disclosure and, thus, no recognition on the part of Pantino that his mechanical oral appliance would in any way be applicable to or capable of treating the functional somatic syndromes. The fact that the Pantino oral appliance can additionally treat the symptoms of TMJ and bruxism in no way leads one skilled in the art to conclude that it can be used to treat functional somatic syndromes generally. Thus, the claimed treatment methods are not taught or suggested.

As noted previously, Thornton discloses a device (10) with an insertable oral section comprised by an upper arch (12) and a lower arch (14). A CPAP system may be associated with or connected to the device (10). In a similar manner to Pantino, Thornton discloses nothing more than a conventional CPAP system which is well-known for treating snoring, sleep apnea, and like sleep disorders. The fact that a device such as that disclosed by Thornton could be used as an apparatus or component to accomplish, in part, the claimed methods in claims 1 and 12 does not in and of itself render independent claims 1 and 12 obvious whether considering Thornton alone or in combination with Pantino or vice versa. Nowhere in Thornton is it suggested that a CPAP device should be used to treat a patient having a functional somatic syndrome or symptom thereof, and the disclosed uses of the Thornton device are limited to the well-known treatment of snoring, obstructive sleep apnea, and other sleep disordered breathing.

The accompanying Sanders Declaration indicates that one skilled in the art reading Thornton would not be directed to use the Thornton device for treating patients suffering from functional somatic syndromes. The Sanders Declaration indicates that the device disclosed in Thornton is intended to treat sleep disordered breathing such as snoring and sleep apnea using positive airway pressure therapy. The Sanders Declaration further indicates that the device is not

intended to or disclosed in any way as being suitable for treating functional somatic syndromes. The Sanders Declaration concludes that until Applicant's recent disclosure, the use of a CPAP device to treat functional somatic syndromes was unknown and, consequently, untried and such a device would not have been used by one skilled in the art to treat a functional somatic syndrome, and it would be non-obvious to do so.

In view of the foregoing, as with Pantino, Thornton does not disclose or suggest a possible or likely relationship between inspiratory airflow limitation during sleep and the functional somatic syndromes and, thus, provides no teaching, suggestion, or motivation for the use of positive airway pressure therapy in the treatment of functional somatic syndromes. Accordingly, there is no reason to conclude that one having skill in the art would have been motivated to combine the CPAP system of Thornton with the mechanical treatment of sleep disordered breathing in Pantino to treat a patient suffering from a functional somatic syndrome, as echoed in Paragraphs 8-9 of the Sanders Declaration. It is only Applicant's disclosure that identifies a causal connection between an inspiratory airflow limitation during sleep and the functional somatic syndromes and identifies a corrective remedy in the form of upper airway stabilization.

It is axiomatic that a new use of a known apparatus constitutes a patentable invention. See 35 USC §100(b) and §101. Applicant's use of airway stabilization, positive airway pressure therapy, in the present instance, for the treatment of a patient having a functional somatic syndrome or symptom thereof is such a use, as would Applicant's use of mechanical stabilization as set forth and described in the specification. Again, Applicant's discovery that the functional somatic syndromes can be treated through stabilization of a patient's upper airway with positive airway pressure therapy and/or mechanical stabilization is a pioneering recognition in the medical field and completely unrecognized by Pantino and Thornton.

It is advanced in the final Office Action that one would be motivated to modify the alleged method of treating TMJ disclosed in Pantino to include the CPAP system of Thornton. However, such an assertion is incorrect for the reasons postulated previously, namely that there is no reason to do so as the Pantino device itself provides all the hardware needed to address the physical symptoms associated with TMJ. The foregoing assertion in the final Office

Action is the result of an improper hindsight analysis. Positive airway pressure therapy is a means of preventing or treating a partially collapsed upper airway. According to Pantino, the cause of bruxism is unknown while the causes of TMJ are bruxism, malocclusion (misaligned teeth), trauma, and arthritis (See Pantino, column 1, lines 51-66). None of these potential TMJ causes include or intimate a partially collapsed upper airway. These teachings lead away from the concept of adding CPAP to the Pantino oral appliance, as the oral appliance itself provides the corrective repositioning of the lower jaw, as noted previously. Accordingly, it would not have been obvious to simply add positive airway pressure therapy to Pantino's mechanical oral appliance as postulated in the final Office Action to enhance the treatment TMJ or bruxism because there is no teaching or suggestion of any connection between a partially collapsed upper airway and either TMJ or bruxism in either cited patent, which is the required "teaching, suggestion, or motivation" to combine in this instance. Only in light of Applicant's discovery would the advantage of such a combination be desirable. In fact, the method taught in Pantino suggests that the benefit of treating the symptoms of TMJ and bruxism results solely from mechanical fixation of the mandible, (See Pantino, column 5, lines 25-27). Thus, one employing the Pantino "method" to treat a patient suffering from TMJ would not be motivated to incorporate the CPAP device of Thornton into such treatment method and, as a result, any obviousness rejection based on the combination of these references is improper.

In conclusion, the cited references manifest a complete lack of teaching with respect to treating functional somatic syndromes with an airway stabilization technique. Only Applicant's disclosure provides a teaching with respect to treating a patient having a functional somatic syndrome or symptom thereof with an airway stabilization technique. Again, the fact that, individually, the Pantino mechanical oral appliance and Thornton oral device with CPAP function are capable of possible use in the claimed methods of treating functional somatic syndromes cannot be used as a basis to conclude that the methods set forth in claims 1 and 12 would have been obvious over these references, taken alone or in combination.

The teachings of Kowallik and Bennett directed to a method and device for sleep monitoring and a therapeutic treatment for fibromyalgia, respectively, do not correct the foregoing deficiencies of Pantino and Thornton. Accordingly, it is respectfully submitted that

independent claims 1 and 12 are allowable over the cited references and such is respectfully requested. Claims 5-6, 8-11, 16-17, and 19-20 include all of the limitations of either independent claims 1 and 12 and are also allowable over the cited references for all the foregoing reasons.

V. Conclusion

Should the Examiner have any questions regarding any of the foregoing or wish to discuss this application in further detail to advance prosecution, the Examiner is invited to contact Applicant's undersigned representative at the telephone number provided below.

Respectfully submitted,

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